**Article**

# Evaluation of Eco-friendly Analytical Methods Using Green Chemistry Metrics

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| | Abstract |
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| <br><br>Published on:<br>09.01.2026<br><br>Futuristic Publications 2026\| All rights reserved.<br><br> | Green analytical chemistry advocates for the reduction of hazardous chemicals and reagents, the use of energy-efficient instruments, and the minimization of waste production. In recent years, new trends in developing analytical methods have focused on miniaturization of the sample preparation systems, development of solvent-free or solvent-reduced extraction techniques, and safe and less toxic solvents. The twelve principles of Green Analytical Chemistry stand as basic guidelines for improving the environmental friendliness of analytical procedures. However, in some cases, non-green steps are still inevitable; thus, analysis of the "greenness" of analytical procedures is necessary in order to identify, characterize, and minimize environmental and occupational exposure associated with these procedures. This objective is supported by several analytical assessment tools, which include the Analytical Eco-Scale, Green Analytical Procedure Index (GAPI), and Analytical Greenness Metric (AGREE). All these approaches assess different aspects of an analytical method with respect to its environmental friendliness. The review discusses the key metrics principles and, by presenting examples, their application to a wide range of analytical methods. Besides, advantages and limitations are outlined from a practical user's perspective. The review is expected to foster new ideas and further progress in developing greener analytical approaches. |
| | **Keywords:** Analytical Method Validation,Quality Control (QC), Green metrics, Green analytical chemistry. |

## Introduction

Pharmaceutical validation is more than just a regulatory checklist; it's a cornerstone of the Quality Management System in the drug industry. Its existence is driven by the fundamental need to ensure patient safety and product efficacy.

The central objective is to provide documented evidence—a scientific demonstration—that any procedure, process, equipment, material, activity, or system will consistently achieve the intended results.

● Consistency is Key: Drugs must be made exactly the same way every time. Validation ensures that variations in raw materials, personnel, equipment, or environmental conditions do not compromise the final product's identity, strength, quality, or purity.

● Focus on Prevention: It represents a shift from solely relying on testing the final product (which only provides a snapshot of quality) to building quality into the process itself. If a process is validated, there is a high degree of assurance that every batch produced will meet specifications.

● Regulatory Requirement: As noted, validation was formalized in the U.S. in 1978 and is mandated by current Good Manufacturing Practice (cGMP) regulations worldwide, such as those from the FDA and the European Medicines Agency (EMA).

### The Implementation Phase (Process Validation)

This is the point where the actual manufacturing process is formally studied and proven.Prospective Validation: This is typically performed before the distribution of a new product. It involves extensive testing and documentation of several consecutive commercial-sized batches to demonstrate consistency.

● Concurrent Validation: In certain justified cases, validation is performed during routine production.

### The Enduring Phase (Ongoing Monitoring)

The statement "Validation of a system never truly ends" is vital. This is the stage of Process Maintenance or Continued Process Verification (CPV).

● Change Control: Any proposed change to the equipment, process, or materials must be assessed for its potential impact on the validated state. If the change is significant, q revalidation is required.

● Periodic Review: Systems and processes are subjected to regular revalidation or a periodic review (e.g., every 3-5 years) to ensure they remain in a validated state over time. This includes checking calibration records, maintenance logs, and analyzing process data for drift Waste prevention : It Adopt its strategies that minimize or avoid waste generation in the analysis process.

Atom Economy Develop analytical methods to optimize the use of all materials so that a minimum amount is lost, although this concept is more relevant to chemical synthesis.

### Principle of Green Chemistry:

Wherever practicable, use and make the least toxic chemical possible for people and the environment.

**Design of Non-toxic Reagents**: Choose or design less harmful reagents for analysis.

**Safer Solvents and Additives**: Replace hazardous organic solvents like methanol or acetonitrile with greener alternatives such as water, ethanol, supercritical fluids, ionic liquids, or deep eutectic solvents.

**Energy Efficiency:** Reduce energy use by performing analyses under ambient conditions when possible, and use energy-efficient instruments.

**Use of Renewable Resources**: Employ reagents and materials derived from renewable sources.

**Minimize Derivatization**: Avoid unnecessary derivatization steps; it decreases reagent use and waste production.

**Catalysis**: Wherever possible, use catalytic reagents instead of stoichiometric reagents to minimize waste and improve efficiency.

**Design for Degradability:** Use materials that can easily decompose when disposed of, leaving behind substances that are harmless to the environment.

**Real-Time Monitoring**: Develop methods of analysis that are capable of on-site and real-time analysis, so as to reduce waste and avoid pollution.

**Inherent Safety:** Use substances and processes that minimize the risk of potential hazards like explosions, fires, and accidental release.

**Importance of greeness in pharmaceutical and Environmental analysis:**
1.**Reduces Environmental Pollution**:Conventional analytical techniques depend on harmful solvents, like methanol, acetonitrile, and chloroform.Green analytical techniques minimize or replace these with less hazardous alternatives such as water or ethanol; this aids in reducing:Air pollution, Toxic chemical waste production, Soil and water body pollution

2. **Enhancing Analyst Safety:**
Since green methods avoid or minimize hazardous chemicals, they offer:Reduced health hazards, A safer laboratory environment Fewer risks of chemical exposure or accidents, More Economical:Green analytical methods generally require:Smaller amounts of solvents, Less energy

3. **Miniaturized equipment**
This leads to lower operating expenses in pharmaceutical and environmental labs.

4. **Supports Sustainable**

5. **Pharmaceutical Progress:**Modern pharma industries are adopting:Eco-friendly drug synthesis processes, Green chromatography methods, Energy-efficient analytical tools, Such practices ensure that drug development has minimal detrimental effects on the environment.

**Integration of GAC principles in method design and Validation:**
- **Regulatory Support:**Green methodologies are encouraged by different authorities like USFDA, EMA, and ICH. Implementing green analysis assists in: Meeting regulatory requirements Improving the Safety and Quality of Pharmaceuticals Detect AI of above sentences. Integration of GAC principles in method design and validation :Applying the GAC principles at the method development stage helps make the analytical process greener, safer for users, and more efficient. These principles can be incorporated within a period starting from initial planning to method validation.Eco-Friendly Solvents and Reagents, Use safer solvents like water, ethanol, or ethyl acetate.Avoid hazardous solvents like acetonitrile, methanol, and chloroform.Choose non-toxic, sustainable reagents that are biodegradable.
- Sample Quantity and Waste Reduction:Develop methods that require very small samplevolumes.Reduce consumption of solvents by adopting micro- or nano-scale analysis techniques.Aim for minimal waste formation throughout the entire process.. Using Energy-Efficient Instruments:Opt for those instruments that operate at lower temperatures, take lesser time, and use less energy.Favor compact, portable, or automated systems where possible to minimize energy requirements further.Simplify Analytical Procedures:Develop procedures that avoid unnecessary steps, like derivatization or complicated extraction methods.Choose direct analysis to save time, reduce the use of chemicals, and simplify manipulations.
- Safety and Environmental Impact Assessment:Review all chemicals for toxicity, flammability, and environmental hazards.Consider safer alternatives that eliminate or minimize risks to analysts and the environment.

**Concept of Green Metrics in Analytical Chemistry:**
Green metrics are quantitative means by which the environmental sustainability of an analytical method is determined.They enable chemists to evaluate the analytical process regarding its ecological impact, safety level, and overall sustainability by providing numerical or descriptive evaluations.
In other words, green metrics reflect the degree of greenness of an analytical method.

**Definition**:
Green metrics in analytical chemistry are formal assessment tools designed to quantify how well an analytical method conforms to the principles of GAC.
These metrics take into consideration chemical consumption, energy requirements, waste production, and safety aspects, among others.

**Purpose of Green Metrics:**

Green metrics serve a variety of purposes:

1. Assess Environmental Impact:Determine the toxicity of solvents, Assess waste generated.Energy consumption analysis

2. Compare Analytical Methods:They help compare:Conventional methods with greener alternatives Two or more newly developed techniques

3. Supporting Methodology Development:Researchers can also optimize methods for Reduction in the use of harmful solvents Limiting sample or reagent amounts Choosing safer and renewable materials

4. Ensure Alignment with GAC Principles:Green metrics verify whether a method follows:The principles of Green Analytical Chemistry Relevant regulations in pharmaceutical and environmental fields

5. Improve Sustainability and Safety: They promoteEco-friendly analytical approaches Safer working conditions for laboratory personnel Lower operating costs owing to reduced waste generation

The two general assessment methods for an analytical method to be considered green include qualitative and quantitative approaches. These approaches offer criteria to chemists on the degree of greenness, sustainability, and safety of the methods

**Qualitative Assessment Approaches:**

Definition:Qualitative approaches describe the environmental friendliness of a method by using descriptive, visual, or categorical indicators rather than numbers.They provide an overall view, not an exact measurement.

Key Features:The use of color schemes, symbols, and charts are some of the visual tools that should be employed.Emphasize descriptive assessment, Simple to read and interpret Useful for quick comparisons between methods.

**Advantages of incorporating green metrics in analytical work flows :**

- Encourages Eco-Friendly Practices

Green metrics can identify processes that generate harmful waste, make use of toxic chemicals, or use too much energy; such identification in turn will spur the laboratories toward greener alternatives.

- Improves Analyst Safety

Green metrics identify dangerous reagents and procedures involving risk, thus facilitating the use of safer materials and conditions that minimize risks for laboratory workers.

- Minimizes Waste and Resource Usage
- These metrics enable chemists to minimize the usage of solvents, reagents, and amount of samples, which, in turn, reduces the amount of waste produced. 4. Improves Methods' Performance Green metrics contribute to the creation of simpler, quicker, and more streamlined analytical methods which have fewer steps, with low energy usage. 5. Operations Become Cheaper Taken together, less use of chemicals, reduced waste, and lower energy consumption mean significant financial savings for a laboratory.

**Analytical Eco scale in green metrics :**

The Analytical Eco-Scale is a numerical tool for assessing environmental friendliness of an analytical procedure. It provides a score that reflects how well the method follows the principles of Green Analytical Chemistry.

Concept:The Eco-Scale starts with a perfect score of 100.From this value, penalty points are deducted depending upon the environmental impact of the method. The higher the remaining score, the more environmentally friendly the analytical method.

**Parameters Considered in the Analytical Eco-Scale and Assigned Penalty Points:**

The Analytical Eco-Scale considers various factors contributing to the environmental friendliness of an analytical method. Each factor receives penalty points according to its safety and environmental impact, which are then subtracted from the starting score of 100.Nature and Hazard Level of Reagents:All reagents are rated on the hazards they pose: toxic, flammable, or corrosive.Highly hazardous or toxic chemicals → Higher penalty points, Low-risk or less harmful reagents → Lower penalty points.

Quantity of Reagents and Solvents, The amount of chemicals directly influences the score.Large volumes of solvents or reagents used → more penalty points, Using smaller or fewer quantities → Fewer penalty pointsEnergy

Needs :Energy-intensive instruments or processes with longer duration have greater environmental impact.High energy use: extended heating, high pressure, etc. → Penalty points added, Reduced energy consumption → Negligible penalty

1. Waste Generation:The Eco-Scale takes into consideration the amount of waste generated during analysis.Producing larger amounts of waste → More penalty points. Producing minimal waste → Lower penalty points
2. Safety and Occupational Risks:Anything that puts analysts in harm's way adds penalty points. Hazardous operations or handling of toxic substances. → penalty points assigned. Safe, automated or low-risk actions → Few, if any, demerit points.

- **Advantages of the Analytical Eco-Scale**

1. Easy and Convenient to Apply

The operation of the Eco-Scale is straightforward since it requires only basic information on reagents, waste, and energy use. No complicated calculations are necessary.

2. Provides a Clear Numerical Rating

It provides a specific, quantifiable score that reflects how green an analytical method is; thus, objectivity is assured.

3. Allows for Comparison Between Methods

The Eco-Scale scores allow easy comparison of various analytical techniques against each other.

4. Considers a wide range of environmental factors.

It assesses several factors, including chemical toxicity, the amount of reagent used, waste production, energy consumption, and safety; thus, the analysis is comprehensive.

5. Promotes the Development of Greener Methods

The Eco-Scale identifies steps with high penalty points, guiding the researcher to improvement and greener alternatives in method optimization.

**Green Analytical Procedure Index (GAPI) :**

Green Analytical Procedure Index (GAPI) is a comprehensive metric used to determine how environmentally friendly an analytical method is by using a color-coded pictorial representation.

1. **Concept of Color-Coded Pictogram Evaluation:**

GAPI employs a pictogram composed of 15 individual fields grouped into five main sections, each reflecting a different stage of the analytical process.Color Interpretation,

- Color    Interpretation
- Green    Environmentally safe or acceptable
- Yellow  Moderate environmental impact, indicating possible improvement
- Red       Significant environmental burden or poor greenness

Pictogram Layout, The pictogram illustrates the greenness of every stage in an analytical workflow, including:Sample collection, Sample preparation, Use of reagents and solventsWaste generation and safety aspects. Each component is assigned a color based on its ecological impact.Overall meaningA mainly green pictogram signifies a sustainable procedureA mixed-color pictogram indicates both positive and negative features. A red-dominated pictogram reflects a method with substantial environmental drawbacks

GAPI aims to be: Easy to interpret, Visually intuitive, Comprehensive, covering all stages from pre-analytical to post-analytical activities

**Evaluation Parameters and Scoring Approach**:

GAPI evaluates 15 criteria divided into five categories. Each criterion receives a green, yellow, or red rating.

3.A. Sample Collection:Nature of sampling (destructive or non-destructive)Transportation needs, Preservation or storage conditions

A. Sample Preparation:Complexity of preparation steps, Need for equipment (heating, extraction, etc.)Toxicity of reagents Solvent volume used , Amount of waste produced
B. Reagents and Solvents:Chemical hazard level, Quantity of reagents, Stability of prepared solutions

C. Analytical Techniques / Instrumentation:Energy demand of instruments, Safety concerns Degree of automation, Sample throughput. Scoring Method:Instead of numerical scoring, GAPI relies on visual color coding.Assessment considers factors such as:Type and quantity of chemicalsDerivatization requirements, Operating conditions (temperature, pressure)Waste toxicity and volume, Energy usage, Unlike tools like AGREE or NEMI, GAPI is descriptive rather than based on quantitative scoring.

## Application in Chromatographic and Spectrophotometric Methods

A. Chromatographic Techniques:GAPI is widely applied to:HPLC, GC, UHPLC, TLC, LC–MS/MS

Role of GAPI:Judges the environmental impact of common solvents (e.g., methanol, acetonitrile often rated red)Evaluates power consumption and instrument demands. Encourages greener choices such as:Supercritical $CO_2$ in SFC, Water/ethanol mobile phases. Reduced column length and flow rates

Example:Conventional HPLC with toxic solvents and high-pressure pumps may display:Red for solvent hazard, Yellow for energy use, Green for automation

B. Spectrophotometric Techniques:GAPI works well for techniques like UV–Vis, IR, and fluorescence because they typically:Require small quantities of chemicals, Operate at low energy, Generate minimal waste. Improvements that boost greenness include:Replacing organic solvents with water, Using micro-scale cuvette, Minimizing reagent consumption, Spectrophotometric methods often score greener overall than chromatographic ones.

Strengths and Weaknesses.

- **Strengths:**

 Provides a complete view of the analytical process

 Simple, visual, and easy to interpret

 Applicable to numerous analytical approaches

 Highlights areas where greener alternatives are possible

 Uses clear color-coding for straightforward assessment

- **Weaknesses:**

 Lacks a standard numerical score

 Some level of assessor subjectivity

 All parameters carry equal weight, regardless of relevance

 Ignores indirect environmental costs like instrument manufacturing or recycling systems

 Small improvements may not significantly affect color rating

Summary purpose. To assess sustainability of analytical procedures. Evaluation Style      Color-coded chart with 15 parameters. Applications:Chromatographic, spectrophotometric. Weaknesses:No numeric score, subjective elements

## Analytical GREEnness (AGREE) metric overview and rationale for development :

Summary and Purpose.

AGREE is a modern metric, designed to quantify the environmental sustainability of an analytical method. It stands directly on the 12 Principles of Green Analytical Chemistry and provides both a numerical greenness score and a circular visual diagram for ease of interpretation.

## Integration of 12 Principles of Green Analytical Chemistry:

AGREE was developed to overcome the shortcomings of earlier greenness-evaluation tools, which often focused on only a few aspects such as hazards related to solvents or the production of waste. In contrast with the older systems, AGREE considers all 12 GAC principles in evaluating each analytical method.

Each GAC principle is given a specific scoring algorithm and weight in the AGREE software.

GAC Principle AGREE

1. Direct analytical methods Whether sample preparation or extraction is required

2. Small sample amounts How much sample is required

3. Low energy consumption: energy requirements of instruments, time, and temperature

4. Use of reusable/renewable materials ↓ Preference for green solvents and renewables

5. Avoid derivatization: Use of direct analysis without chemical transformation

6. Safer solvents & reagents:Toxicity and environmental profile

7. Waste minimization:Amount of waste per sample

8. Miniaturization Micro-scale or nano-scale operations

9. Real-time monitoring-On-line or continuous analysis capability

10. Multi-analyte capability\tNumber of analytes measured in one run

11. Operator safety:Threats to personnel

12. Overall environmental impact Broader ecological and life-cycle considerations
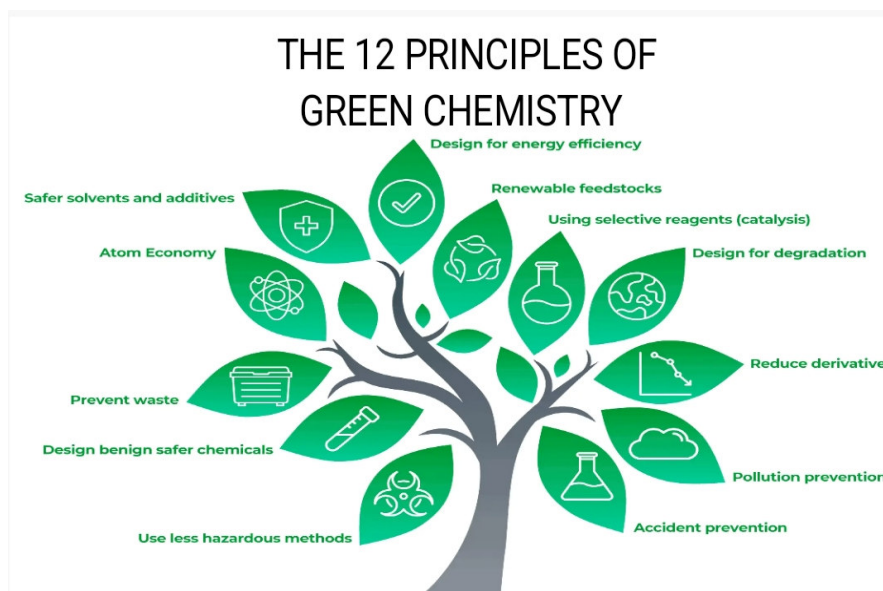


Reason for this design, Ensures a complete, balanced, and objective greenness evaluation, Avoids overemphasizing single aspects, such as solvent toxicity, Helps analysts design greener methods in line with current sustainability expectations.

**Software based evaluation and score interpretation:**

AGREE is freely available software, either as a web or desktop tool. Users input relevant method details, and the tool automatically calculates greenness.

Main Features:Circular, clock-like diagram with 12 segments. Color scale, in green → yellow → red, indicating greenness level.Built-in weighting for each GAC principleExportable results and diagrams.

Scoring Method:Each of the principles is scored from 0 (least green) to 1 (most green).The result is a final overall score ranging from 0.00 to 1.00.Score Interpretation

| Score\tMeaning | |
|---|---|
| 0.85–1.00 | Very sustainable technique |
| 0.60–0.84 | Generally green; small improvements possible |
| 0.40–0.59 | Moderate greenness |
| 0.20–0.39 | Not very green |
| 0.00–0.19.Environmentally poor method. This unified score makes it easy to compare various analytical approaches and optimize greener alternatives. | |

**Comparitive examples of Eco-Scale versus GAPI**

A. Eco-Scale.Strengths:Simple and quantitative Useful especially for organic analysis and sample prep.Limitations:Does not cover all GAC principles, Less comprehensive; limited assessment of instrumentation and operational factors

B.  GAPI: Green Analytical Procedure Index:Method: 15-segment, color-coded pictogram mapping greenness across the workflow.Strengths:Easy visual interpretation. Evaluates the entire analytical process-from sampling to detection, Limitations:No numerical score. Color judgments can be subjective. Does not give equal weight to each principle

C.  AGREE Method: Evaluates each of the 12 GAC principles individually and as a whole using software. Strengths: Most comprehensive and scientifically aligned tool Direct correspondence with all 12 GAC principles It provides both a visual diagram and a single quantitative score. Limitations: Requires specific data entry Accuracy relies on detail and correctness of user information

**Other Green assessment Tools** :

**National Environmental Methods Index (NEMI):**

NEMI represents one of the earliest qualitative frameworks designed to determine how environmentally safe an analytical method is. This is done by using a simple four-section pictogram to represent the evaluation.Main Evaluation Criteria:Presence of persistent, bioaccumulative and toxic (PBT) substancesGeneration of hazardous waste, Use of corrosive chemicals, Total waste output:Every green requirement that is met is highlighted in green within the pictogram.Fast and easy to understand, Works well as a preliminary means of screening for method greenness, Provides basic information only, Does not provide an in-depth review of the complete analytical work process.

**Carbon Footprint and Energy Consumption Methods**

These methods quantify the environmental burden of an analytical process through energy consumption and greenhouse gas emissions, especially $CO_2$., Carbon Footprint Assessment, This measures the quantity of carbon dioxide emitted during the analysis. It includes the emissions associated with:Operating instruments.Heating and cooling processes, Waste handling, Manufacturing of Reagents, Energy Consumption Study, Defines the quantity of electrical energy (kWh) consumed in sample preparation, instrumentation, and analysis. Why It Matters, Identifies steps with high energy demand, Encourages energy-efficient equipment and shorter analysis times.

**Life Cycle Assessment in Analytical Chemistry**

LCA takes into account the environmental impact of an analytical method all the way from the origin of materials to final waste management.

LCA Stages

1.  Extraction of raw materials (solvents, chemicals)
2.  Manufacturing and transport
3.  Operational phase: Instrument energy, reagent consumption
4.  Processing and recycling of waste.

**Greenness Index (Composite Assessment Method):**

The Greenness Index combines several green chemistry indicators into one overall score, Factors Considered, Chemical toxicity, Amount and type of waste generated, Energy use, Safety hazards. Environmental impact. Sustainability of analytical processes, Output, Provides one combined greenness score, Often presented in multi-criteria graphs or ranking lists.

 Purpose:Offers a balanced and accurate overall assessment, Allows for more reliable comparison of analytical methods.

**Main features of NEMI:**

Visual representation: The four quadrants map the compliance of key environmental criteria and make it easy to compare multiple analytical methods.

Greenness criteria:PBT (Persistent, Bio-accumulative, and Toxic): Identifies if harmful compounds are involved in the method.

Hazardous waste: Indicates whether procedure avoids generation of hazardous waste, specifically solvents classified as K, F, P, or U.

Corrosiveness: Tests whether the sample pH value stays within a safe range (2–12). Waste generation: The total waste generated is less than 50 g.

Purpose: NEMI helps analysts identify or modify environmentally sustainable methods, improving the comparability of data across agencies while reducing costs and ecological impact. Limitations: As a qualitative evaluation tool, NEMI provides only a general visual assessment, not numerical scores. It also does not take into consideration other environmental aspects, such as energy use or instrumental efficiency.

**Comparative Evolution of Green Metrics in Analytical Chemistry:**

Green metrics assessment determines the analytical procedure's environmental sustainability. Over time, tools such as Eco-scale, GAPI, AGREE, and NEMI have been developed that offer evaluations of method greenness in increasing detail and visual form.

**Comparative Summary of Eco-scale, GAPI, AGREE :**

Limitations:NEMI Qualitative Simple 4-quadrant symbol PBT chemicals, corrosivity, hazardous waste, total waste Easy, fast screening tool Evaluates very few parameters; does not provide numerical scoring

Eco-scale Semi-quantitative Score out of 100 Penalty points for reagent hazards, waste, energy demand, safety concerns Enables quantitative comparison; focuses on hazardous chemicals Does not include full lifecycle factors; penalty scoring subjective

GAPI Qualitative & visual Five-segment, star-shaped figure comprising 20 fields Entire analytical workflow (sampling → storage → preparation → measurement → waste) Overall stepwise visualization; identifies problematic steps No single score; color judgment can vary. AGREE Quantitative + graphical Circular diagram with greenness score (0–1) Based on 12 principles of Green Analytical Chemistry Holistic, visually appealing, provides combined score Requires detailed method data; weighting may vary

**Strengths, Weaknesses and Suitable Applications of Each Metric:**
1. NEMI:Strengths, Very easy to interpret, Useful for quick comparison of traditional methods, Weaknesses, Considers only a few environmental factors. Not suitable for modern or miniaturised procedures. Most suitable for:Classical wet chemistry, titrations, and older techniques with straightforward workflows.
2. Eco-scale:Strengths. Provides a numerical score for easy comparison. Well suited for chromatographic and spectroscopic techniquesEmphasizes reagent toxicity and waste. Weaknesses. Sampling or energy aspects are not included.Penalty points might vary between users.Best suited for:HPLC, GC, UV–Visible, FTIR, electrochemical analysis.
3. GAPI:Strengths. Evaluates the entire process of analysis. Detailed and illustrative color-coded diagram. Widely useful in pharmaceutical and environmental laboratories. Weaknesses. No final combined greenness score. Some of the procedural steps may appear over-penalized.Most suitable for:Chromatography, extraction methods, spectrometric techniques, and analyses with complex sample preparation.
4. AGREE:StrengthsCovers all 12 Green Analytical Chemistry principles. Allows customization and holistic evaluation. Produces both a visual output and a final score. Weaknesses, Requires extensive method information, May be difficult for beginners to interpretMost suitable for:Advanced, highly green methods such as UHPLC, SFC, microscale extractions, and flow-based systems.

**Practical Aspects of Implementing Green Metrics in Laboratories:**
1. Training Requirements:Training of personnel on the principles of sustainability. Green metrics often need to be incorporated into SOP revisions.Cost Factors: reener solvents (e.g., ethanol) can be more expensive than comparable alternatives. Miniaturized systems reduce long-term costs.
2. Redesign Method:The transition from HPLC to UHPLC saves solvents but requires new equipmentWaste Management Practices:Separate organic and aqueous wastes. Employ recycling or recovery strategies
3. Energy Consumption:Use low-energy instrumentation like LED detectors and efficient pumps
4. Regulatory Considerations:Green metrics should meet the regulatory requirements of agencies such as ICH and FDA.

**Green Metrics in Analytical Method Development:**

Green method development focuses on creating analytical procedures that reduce toxicity, waste, energy consumption, and environmental impact without compromising performance.

**Eco-friendly solvent and reagent selection:**

Preferred green solvents include:Water, Ethanol, Ethyl acetate,AcetoneSolvents and reagents to minimize or avoid:Acetonitrile, Methanol, Chloroform, Aromatic solvents (benzene, toluene)Strong mineral acidsGreener approaches:Replace acetonitrile by ethanol/water mobile phases in HPLC. Use enzyme-based reactions instead of corrosive chemicals. Choose reagents with lower GHS hazard ratings

**Miniaturization and automation for resource efficiency:**

Benefits of miniaturization:Sample preparation at the level of microlitersReduced solvent and sample usage. Faster analysesReduced energy.consumptionExamples:Capillary electrophoresisMicrofluidic/ lab-on-chip systemsBenefits of automation:Better precision and reproducibilityImproved safetyIntegrated waste minimizationExamples:FIA, SIA, MPFS systemsAutomated samplersRobotic SPE systems

**Case Studies in Chromatography and Spectroscopy:**

Conversion from HPLC to UHPLC..80–90% solvent savings.Faster separations and higher resolution. Uses small-particle columns requiring less mobile phase

1. Greener Gas Chromatography:Switching helium to on-site hydrogen generation brings lower costs and improved sustainability.
2. Supercritical Fluid Chromatography (SFC):Uses $CO_2$ with a small amount of green co-solvent. Produces less organic wasteExcellent for chiral separations
3. Spectroscopy as a Green Technique. UV–Vis: no need for organic solvents. FTIR: reagent-free and waste-free. Fluorescence: high sensitivity with small sample quantitiesAAS/ICP: high energy demand but no solvent waste

**Role of Chemometrics and QbD in Developing Greener Methods**.

ChemometricsAssists in the optimization of processes with the help of statistical and mathematical tools.Reduces the number of experiments needed. Identifies critical factors such as pH, solvent composition, and flow rate.Enables the prediction of greener operating conditions

Result: waste reduction, less use of chemicals, and more efficient methods --- Quality by Design (QbD) Establishes a structured approach to method development Includes definition of the analytical target profile (ATP) Determines the CMPs of the method Creates a design space that is robust, yet with minimal environmental impact. → Ensures that methods are reliable, efficient, and environmentally friendly.

**Green Metrics in Analytical Method Validation:**

The principles of GAC can be directly applied to the method validation process in order to keep the analytical procedures precise, dependable, and eco-friendly. Green metrics can be used during the validation process to reduce the generation of waste, use fewer hazardous chemicals, and generally improve the ecological efficiency of the analytical process.

**Integrating Green Features into Validation Parameters:**

Each validation parameter such as Accuracy, Precision, Robustness, LOD/LOQ, Linearity, Range, and Selectivity can include greening ASPECTS.

a. Accuracy:Employ smaller sample and reagent volumes without loss of sensitivity.Choose miniaturized techniques: microextraction, scaled-down titrations, or dilute-and-shoot methods.Choose greener solvents: ethanol, ethyl acetate, or water-based mobile phases.
b. Precision (Repeatability & Intermediate Precision):Lower the number of replicate measurements by:Application of statistical tools such as power analysis or DOE.Use autosamplers employing micro-volume injection to minimize the consumption of solvent.

c. Robustness:Apply multivariate DOE to:Reduce the number of robustness trials.Reduce reagent and solvent use.Select operating conditions that are stable but utilize less hazardous materials.
d. LOD & LOQ:Use more sensitive detection systems-fluorescence, MS-to reduce sample and solvent consumption.Improve analyte response, using greener derivatization options when feasible, or derivatization-free approaches.
e. Specificity / Selectivity:Choose methods that avoid unnecessary extraction.Use cleaner sample preparation techniques: QuEChERS, SPME, MEPS.
f. Linearity & Range:Reduce calibration points where acceptable: instead of 7 to 10, use 5.Prepare standards at lower concentrations to minimize the use of chemicals.

**Minimizing Waste and Solvent Use During Validation:**
Green validation mainly focuses on reducing the usage and generation of solvent and waste.
g. Solvent Reduction Approaches:Use shorter HPLC columns (50–100 mm) and narrow-bore columns (2.1 mm ID).Prefer low-toxicity or buffer-free solvent mixtures: water–ethanol, water–ACN with less ACN. Employ UHPLC to reduce analysis time and solvent volume.
h. Waste Reduction Techniques:Prepare samples on a micro-scale.Reduce organic solvents by using SPME or dispersive extraction.Recycle non-hazardous waste when permitted: for example, recycling of mobile phase in isocratic runs.
i. Green Instrumentation Choices:HS-SPME-GC replaces the derivatization steps of GC.Use greener extraction methods, such as MAE, UAE, SFE.Choose instruments or methods that consume less energy and have shorter running times.
j. Experimental Planning:DOE helps in:Reduce the number of validation experiments in total.Lower consumption of solvents and consumables

**Documentation and Reporting of Green Indicators:**
Quantitative and transparent representation is required for green performance in any validation.
Green Metrics in Reports:AGREE score (0–1 with colored chart).GAPI pictogram: 15-segment environmental profile.Eco-Scale value (out of 100; >75 indicates excellent greenness).

**Indicator / Description.**
Solvent consumption: mL per run/day, vs. Older techniques, Waste produced, Quantity or mass per analysis
Hazard level Based on GHS GHScategories

Energy use × Analysis time × instrument power. Sample Size (mg or µL) needed per test run.
k. Summary of Sustainability:A concise statement may include:This method has been validated by using reduced solvent quantities, miniaturization of the prep, and DOE to limit experimental workload. AGREE = 0.72 and Eco-Scale = 85, indicating high environmental sustainability.
l. Comparison with Conventional Methods:Improvement such as:% saving in solvent consumption, Removal of hazardous reagents, % decrease in analysis time
m. Visual Presentation
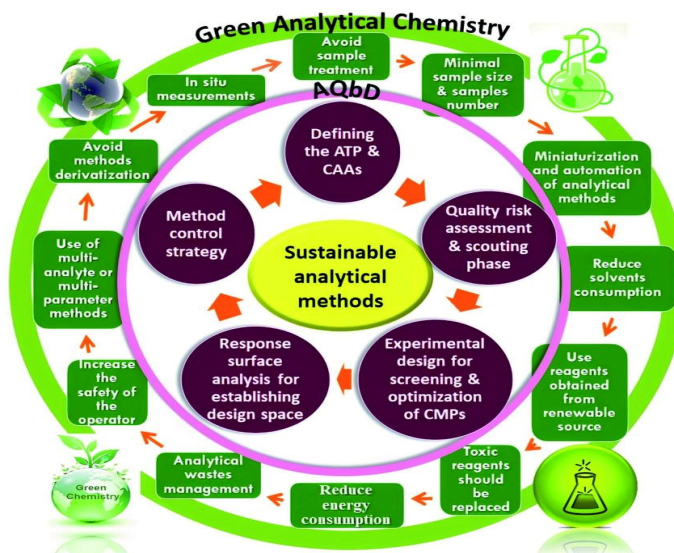
**Include**

GAPI model, Eco-Scale scoring chart, These visuals help reviewers and regulators to easily understand the method's green performance.,Exam-Friendly Summary

Green elements in validation:Reduce experiments, use safer solvents, miniaturize methods, apply DOE.Waste/solvent reduction Use short columns, UHPLC, SPME, QuEChERS; avoid derivatization; recycle waste. Green reporting Include AGREE, GAPI, Eco-Scale; quantify waste, solvent, energy; compare with traditional methods.

**Recent trends and Digital Tools:**

Modern analytical laboratories increasingly use digital platforms, artificial intelligence, and sustainability-focused databases in the development of greener analytical methodologies. These emerging technologies help automate greenness evaluation, recommend safer solvents, and ensure compliance with evolving environmental standards.

**Software and AI-Based Greenness Evaluation:**Digital and AI-driven methods provide a quick, consistent, and unbiased assessment of the greenness of an analytical procedure. These technologies minimize human error and produce visual and numerical outputs.

A. Popular Digital Assessment Tools

AGREE Software 1.

Developed around the 12 Principles of Green Analytical Chemistry.Produces a 0–1 greenness score along with a circular graphical display.Offers automated scoring, making it less subjective than tools such as GAPI or Eco-Scale. Both web-based and desktop versions are available.

2. AGREEprep:Focuses solely on greenness assessment in sample preparation.Evaluates parameters like the consumption of solvent, reagent hazards, extraction efficiency, and energy requirements.
3. iSUSTAIN™ Green Chemistry Tool:Used extensively in industrial settings.Predicts sustainability ratings for chemicals and reagents to aid in the evaluation of process hazards.
4. DOZN™ Green Chemistry Evaluator
5. AI-Based Predictive Systems

AI technologies help:Recommend suitable green solvents for different kinds of separations.Suggest environmentally friendly method parameters: pH, flow rate, temperature.Reduce experimental workload through optimized DoE+ AI algorithms.Examples include:Machine learning solvent-substitution tools. Optimization software for chromatography, such as DryLab, ChromSword, and ACD/Labs platforms

Databases for Sustainable Solvent Substitution:Green analytical chemistry enables the replacement of harmful solvents by safer alternatives. Digital solvent guides and databases facilitate rapid identification of greener alternatives for researchers.

**Sustainable solvent replacement Databases:**
1. CHEM21 Solvent Selection Guide:Categorizes solvents as preferred, cautionary, hazardous or to be avoided Considers toxicity, sustainability, renewability, and biodegradability.
2. GSK Solvent Guide:One of the earliest solvent-ranking systems.Uses a green–yellow–red color scheme.Commonly applied in pharmaceutical development.
3. Pfizer Solvent Tool Similar to the GSK approach but also assesses:Life-cycle impact, Regulatory restrictions, Worker-safety considerations
4. ACS GCI Pharmaceutical Roundtable Guide, Integrates safety, health, and environmental criteria.Offers standardized solvent recommendations for the pharmaceutical sector.
5. Hansen Solubility Parameter (HSP) Database,Suggests solvent replacements with similar solubility characteristics.Useful in replacing harmful solvents such as dichloromethane with environmentally friendly alternatives like ethyl acetate.
6. Databases by PubChem, ECHA. Provide key data on toxicity, biodegradation, and hazard classifications.

Valuable for selecting environmentally compatible solvents according to GHS categories.


**Industrial and Regulatory Developments in Greenness Validation:**
Regulatory authorities and industries are increasingly integrating greenness metrics into analytical procedures, validation, approval, and quality control processes.
A. Regulatory Improvements
1.Inclusion in Standards for Method Validations:Agencies like FDA, EMA, and ICH encourage greener methodologies by promoting, Reduced consumption of solvent, Reduction of hazardous reagents, Environment-conscious analytical design. Green considerations are gradually being weaved into:AQbD: Analytical Quality by Design, Analytical lifecycle management
ICH Q14 guidelines.
2.Green Documentation in Submissions:Now, more corporations include::Greenness assessment summaries: Eco-scale, AGREE, GAPI, Environmental risk assessments for analytical processes
3.Advocate for Green Laboratories:Regulators increasingly stress:Waste minimization, Solvent recycling systems, Safe and sustainable chemical handling practices


**Trends in Industrial Practices:**
1.Adoption of Greener Chromatographic Techniques. Replacing acetonitrile and methanol with greener mobile phases such as ethanol/water.
UHPLC, microflow systems, and SFC significantly reduce the amount of solvents used.
2.Digitization of Method Development:Growing use of computer-aided method development tools.Artificial intelligence-based platforms for predictive chromatographic optimization.
3.Commitment to Sustainability Goals:The pharmaceutical and chemical industries focus on:Meet ESG targets, Reduce environmental footprint, Introduce green solvents into routine QC operations
4.Increased Use of Real-Time Monitoring:Adoption of PAT tools: in-line, on-line, at-line monitoring. Decreases sample handling, the amount of solvent used, and generation of waste.


**Challenges and Future Perspectives of Green Metrics in Analytical Chemistry :**
Green evaluation tools such as GAPI, AGREE, Eco-Scale, NEMI, PMT, and others have undoubtedly significantly enhanced laboratory measurements of sustainability. Notwithstanding such advances, some salient gaps and further developments are still evident.


**Limitations of Current Green Metrics:**
a. Subjective Scoring and Weight Assignments
Many of the existing tools rely on evaluators' judgment, like color coding or penalty point schemes, which might create variability and inconsistencies among different analysts.
b. Inadequate Representation of Environmental Factors
Several indicators do not fully take into account key parameters of sustainability, including:Energy requirements of instruments. Overall carbon emissions, Lifecycle impacts of chemicals and equipment. Toxicity of the waste

vs amount generated,. For instance, while Eco-Scale focuses mainly on hazards of reagents, GAPI focuses on procedural steps without addressing energy or carbon footprint.

    c.    Lack of Integration of Real-Time Data

Most of the green assessments give a snapshot of a method, rather than monitoring its performance. They do not account for:Changes in solvent use during normal operation. Instrument wear and maintenance variations, Long-term waste patterns

    d.    Limited Suitability for Modern Technologies:Advanced systems involving high-resolution MS, microfluidics, or ambient ionization may not be good fits into many of the older greenness metrics frameworks. This is the case especially when methods involve several interconnected steps.

    e.    Lack of strong regulatory support:Agencies encourage sustainability ideas, but they do not require the use of particular greenness tools. Labs therefore pick different metrics, which reduces consistency in this area across the industry.

**Need for Harmonization and Regulatory Acceptance:**

    f.    Standardisation of Evaluation Across Laboratories:A set of uniform criteria is necessary for comparison across labs. Currently, tools like Eco-Scale, GAPI, AGREE, and NEMI often give different results for the same method because of different principles and scoring systems applied.

    g.    Integration of Green Requirements within Regulatory Guidelines

Future regulatory documents may include :Minimum statutory levels of greenness, Requirements to report on environmental impact. Approval of specific validated green assessment tools, The steps taken would spur greener method development and validation.

    h.    Establishing International Frameworks:Bodies such as IUPAC, ISO and OECD could promote global harmonization by standardizing definitions for:Waste categories, Hazard classifications,Energy consumption limits,Green analytical performance criteria

    i.    Development of a Combined Green Index:A common index that encompasses all aspects of toxicity, waste, energy usage, carbon footprint, and safety will enhance comparability and advance regulatory acceptance

**Opportunities Through Automation, Data Analytics, and AI**

    A.    Automatic Greenness Evaluation:Modern instruments generate continuous operational data – flow rates, pressures, run times. This information can be used to automatically calculate:Real-time solvent and resource consumption, Waste generation, Energy consumptionAutomated GAPI or AGREE scoring

    B.    AI-Enhanced Method Development:Machine learning enables the optimization of:Solvent selection and greener alternatives, Mobile-phase compositions. Column specifications. Operating parameters such as temperature or gradient. AI can measure the environmental impact long before actual experimentation starts.

    C.    Use of Digital Twins for Green Optimization:Simulated models allow comparisons to:Chromatographic conditions. Energy requirements of GC, LC, and UHPLCWaste production scenarios. This reduces experimental workload and promotes eco-friendly decisions.

    D.    Integration with LIMS platforms:LIMS can have integrated greenness dashboards to monitor:Hazardous chemical usage Waste generation limitsCarbon footprint per analytical method

    E.    AI-based recommendation systems:These systems can suggest:Safer and greener solvent substitutes Miniaturized sample preparation approaches.Low-energy detection options AI can also consider several analytical strategies and choose the most sustainable among them.

    F.    Cloud-Based Repositories of Green Methods:Central databases containing validated green methods support. Benchmark comparison. Easy transfer of methodsRegulatory review and auditing

Need for Harmonization:

Harmonization of standards, incorporation within regulatory guidelines FDA/ICH, international frameworks IUPAC/ISO, and elaboration of a unified greenness index. Future Prospects: Automation of greenness evaluation, AI-assisted optimization, digital simulations, monitoring with LIMS, and green method repository development.

If you wish, I can also change this to: ✔ exam notes format ✔ a short bullet-point summary a long descriptive paragraph ✔ a table comparing metrics: GAPI vs. AGREE vs. Eco-Scale

**Summary of key findings :**
Green Analytical Chemistry focuses its efforts on making analytical procedures greener by eliminating or reducing toxic chemicals, decreasing energy requirements, and minimizing the generation of waste.
Tools like NEMI, GAPI, AGREE, and the analytical eco-scale enable researchers to measure and visualize how sustainable an analytical method is The use of digital platforms is growing rapidly, along with the application of AI-driven evaluation systems and automated greenness-checking tools to speed up the assessments and make sustainability evaluations uniform.. Eco-friendly solvents, compact analytical instruments, and cleaner sample preparation methods are some of the developments further making today's analytical techniques 'greener'.

**Emphasis on the Role of Green Metrics in Sustainable Analytical Science.** Green metrics are significant guides to assist scientists in the selection of safer chemicals, less toxic solvents, and equipment that consumes less energy.They present unbiased, transparent comparisons of various analytical procedures with respect to their environmental impact..
The metrics below further assist labs in complying with the standards of sustainability and contribute to reducing operation costs.
Green metrics serve to indicate where improvement is needed, thus helping researchers redesign or upgrade their methods in an ecologically friendly manner.
Overall, they promote responsible and sustainable practices in scientific and industrial laboratories.

**Outlook for Future Analytical Method Design:**
Analytical procedures of the future will be developed with sustainability as a central focus rather than as an optional feature. More reliance will be placed on AI, automation, and machine learning for the selection of solvents, method optimization, and the generation of instant greenness evaluations.
Miniaturized and portable equipment, such as microfluidic devices and lab-on-a-chip systems, will become increasingly available, using extremely small samples and generating minimum waste.Solvent-free or low-solvent extraction techniques, such as SPME and SBSE, along with supercritical fluid extraction, will likely see further expansion.The adoption of renewable solvents, biodegradable chemicals, and energy-saving technologies will continue to rise.
Besides this, the development of internationally accepted green metrics will standardize the sustainability assessment of laboratories worldwide.

**Analytical Method Validation:**
According to ICH Q2 (R1), method validation can be defined as, "Establishing a documented proof, which provides a High degree of assurance that a specific process will consistently produce a desired result at its prearranged Specifications and quality characteristics."
Simply, it is the process of indicating that analytical procedures are suitable for their planned use and that they support  The identity, quality, purity, and potency of the drug substances and drug products. Method Validation is requiring when A new method has been developed and when established methods are used in different laboratories and different
**Analysts**.: The performance characteristics required to validate various methods by using various guidelines such as USP, ICH,  FDA, European guidelines etc.
**According to USP :** The analytical parameters can be validated are accuracy, precision, specificity, detection of limit, quantitation limit,  Linearity, range, ruggedness and robustness.
**According to ICH :** The analytical parameters can be validated are accuracy, precision, specificity, detection of limit, quantitation limit,  Linearity, range, system suitability and robustness.
**According to FDA :**The analytical parameters can be validated are accuracy, precision, specificity/selectivity, detection of limit,  Quantitation limit, linearity, range, system suitability, reproducibility, sample solution stability and robustness.

**According to European guidelines :**The analytical parameters can be validated are accuracy, precision, specificity, detection of limit, quantitation limit, Linearity and range.

Analytical methods need to be validated, verified, or revalidated in the following instances:

• Before initial use in routine testing

• When transferred to another laboratory

• Whenever the conditions or method parameters for which the method has been validated change (for example, An instrument with different characteristics or samples with different matrix).

**Types of analytical procedures to be validated**

The following types analytical procedures to be validated.

• Identification tests

• Quantitative tests for impurities content

• Limit tests for the control of impurities

• Quantitative tests of the active moiety in samples of drug substance or drug product.

**Identification tests :**Identification tests are used to ensure the identity of an analyte in a sample. This is normally achieved by comparison of a property of the sample (e.g., spectrum, chromatographic behavior, chemical reactivity, etc.) to that of a reference standard.

**Quantitative tests and Limit tests for impurity control**

Testing of impurities can be performed by using a quantitative test or a limit test for the impurity in a sample. Different validation parameters are required for a quantitative test than for a limit test;. Quantitative tests of the active moiety in samples of drug substance or drug productIn this type, assay procedures are used to measure the analyte present in a given sample. The assay represents a quantitative measurement of the major component(s) in the drug substance.

**Objectives**

• To obtain consistent, reliable and true data.

• To demonstrate that it is suitable for its intended purpose.

• To form a base for written procedure for production and process control which are designed to assure that the Drug products have the identity, strength, quality and purity.

• To hold the quality, safety and efficacy in final product.

• To control each step of manufacturing process.• To produce the best analytical results possible.

**Advantages:**

• It builds a degree of confidence, not only for the developer but also to the user.

• Produces quality products

• Reduce the product cost by increasing efficacy, few reject and longer equipment life.

• Helps in optimization of process or method.

• Helps in process improvement, technology transfer related products validation and increased employee Awareness.

• It eliminates testing repetitions and leads to better time management in the end.

**LIMITATIONS**:

1. Limited Scope:
   - Specificity:Validated methods may not be applicable to all sample types, matrices, or concentrations.
   - Interference: Endogenous or exogenous substances can interfere with the analytical method, affecting its accuracy.
2. Method Performance:
   - Precision and Accuracy: Method validation may not guarantee perfect precision and accuracy, especially at low concentrations or in complex matrices.
   - Linearity and Range: The validated method may not be linear or accurate over the entire concentration range.

3. Sample Preparation:
- Sample Stability: Samples may degrade or change during storage, handling, or preparation, affecting analytical results.
- Matrix Effects: Sample matrices can affect the analytical method's performance, leading to inaccurate results.

4. Instrument and Equipment:
- Instrument Variability:Different instruments or equipment can produce varying results, affecting method reproducibility.
- Instrument Maintenance: Instrument malfunction or poor maintenance can impact method performance.

5. Analyst and Laboratory:
- Analyst Variability:Different analysts or laboratories may produce varying results, affecting method reproducibility.
- Laboratory Conditions: Environmental conditions, such as temperature and humidity, can impact method performance.

6. Reference Standards:
- Availability and Quality:Reference standards may not be readily available or may be of poor quality, affecting method validation.
- Certification and Traceability: Reference standards may not be certified or traceable to a recognized standard, impacting method accuracy.

7. Method Updates and Changes::
- Method Drift: Methods can drift over time due to changes in instruments, reagents, or analysts, affecting method performance.
- Method Updates:Changes to the analytical method can require re-validation, which can be time-consuming and resource-intensive.

8. Regulatory and Compliance:
- Regulatory Requirements:: Method validation must comply with regulatory requirements, which can be complex and time-consuming.
- Documentation and Record-Keeping: Method validation requires extensive documentation and record-keeping, which can be burdensome.

**Key Parameters of Analytical Method Validation**:
Analytical method validation involves assessing several performance characteristics to ensure the method is suitable for its intended purpose. These parameters are crucial for establishing the reliability and quality of the results obtained.
It is defined as the percentage of the mass of the desired product relative to the mass of all non-benign reagents used in its synthesis. The reagents here may include any used reactant, solvent or catalyst.

**Advantages of the Analytical Eco-Scale:**
1. Easy and Convenient to Apply
The operation of the Eco-Scale is straightforward since it requires only basic information on reagents, waste, and energy use. No complicated calculations are necessary.
2. Provides a Clear Numerical Rating
It provides a specific, quantifiable score that reflects how green an analytical method is; thus, objectivity is assured.
3. Allows for Comparison Between Methods
The Eco-Scale scores allow easy comparison of various analytical techniques against each other.
4. Considers a wide range of environmental factors.
It assesses several factors, including chemical toxicity, the amount of reagent used, waste production, energy consumption, and safety; thus, the analysis is comprehensive.
5. Promotes the Development of Greener Methods
The Eco-Scale identifies steps with high penalty points, guiding the researcher to improvement and greener alternatives in method optimization.Main features of the AGREE metric include:

All-inclusive: The aforementioned factors include, but are not limited to, reagent toxicity, the generation of waste, the consumption of energy, and automation and operator safety.

Quantitative and Visual Output: the tool produces a single numerical value describing the overall greenness of the method, with an accompanying clock-like diagram showing strengths and weaknesses with respect to the 12 GAC principles. Ease of Use: The software AGREE is freely available, open source, and user-friendly, making analytical method evaluations rapid and accessible. Related Development: The later introduction of the AGREEprep extension provided a more focused evaluation of the greenness of sample preparation steps, normally representing the most significant environmental impact.

National Environmental Method Index :

NEMI stands for National Environmental Methods Index, and is both a database and an evaluation tool, intended to compare the environmental sustainability of analytical methods. It outputs its information in a four-quadrant pictogram, showing a different environmental criterion within each quadrant. Each of these quadrants will turn green when that particular criterion has been satisfied, allowing users a fast, visual indication of how "green" a method is.

**Main features of NEMI:**

Visual representation: The four quadrants map the compliance of key environmental criteria and make it easy to compare multiple analytical methods.
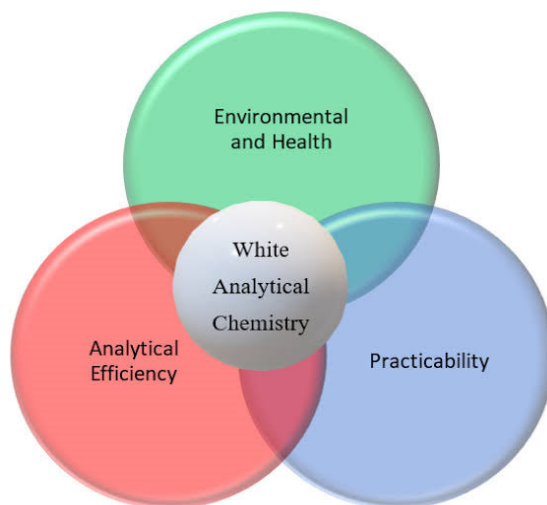
Greenness criteria:

PBT (Persistent, Bio-accumulative, and Toxic): Identifies if harmful compounds are involved in the method.

Hazardous waste: Indicates whether procedure avoids generation of hazardous waste, specifically solvents classified as K, F, P, or U.

Corrosiveness: Tests whether the sample pH value stays within a safe range (2–12). Waste generation: The total waste generated is less than 50 g.

Purpose: NEMI helps analysts identify or modify environmentally sustainable methods, improving the comparability of data across agencies while reducing costs and ecological impact. Limitations: As a qualitative evaluation tool, NEMI provides only a general visual assessment, not numerical scores. It also does not take into consideration other environmental aspects, such as energy use or instrumental efficiency.



**Conclusion**

The suitability of a standard test method is determined by the singularity of pharmaceutical products and their Applications. The method development application to Standard test methods is expected to result in the more Meaningful generated data. As a conclusion, enhanced Data quality enables decisions to be made with Increased confidence. Not only can troubles be Observed quickly when reliable data is available, but Solutions become also easier to find. The method Development process along with validation ensures the Applicability and reliability of

the data. The result is a more detailed understanding of the Standard test methods and an additional insight into the Relationship between test methodology and product Performance. It is important to validate an advanced Method.Because if the method cannot be reproduced, The method is meaningless. Validation is always a Balance between costs, risks and technical possibilities.

Therfore, strong in-service training will ensure Successful method development and validation

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